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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lionel Tarassenko

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EXAMINER

SORIANO, BOBBY GILES

ART UNIT

PAPER NUMBER

3769

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,365	Applicant(s) TARASSENKO ET AL.	
	Examiner Bobby Soriano	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14, 15, 17-21, 23-25, 27, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14, 15, 17-21, 23-25, 27, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/03/06; 3/18/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 10, filed October 1, 2009, with respect to the rejection of claims 1-11, 14, 15, 17-21, 23-25, 27 and 37 under 35 U.S.C. Section 112, second paragraph, have been fully considered and are persuasive. The rejection under 35 U.S.C. Section 112, second paragraph, of claims 1-11, 14, 15, 17-21, 23-25, 27 and 37 has been withdrawn.

Applicant's arguments, see pages 10-14, filed October 1, 2009, with respect to the rejection of claims 1-11, 14, 15, 17-21, 23-25, 27, 36, and 37 under 35 U.S.C. Section 103 in view of Walker et al. and Schulze et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection has been made in view of the applied prior art below.

Note to Applicant Regarding Claim Interpretation

The term "for" followed by an action (i.e. "displaying") in the claims may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-11, 14, 15, 18, 19, 23-25, 27, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacCarter US Patent Application 2002/0082867 in view of West US Patent Application 2002/0013517 and further in view of Iliff US Patent Application 2001/0029322.

MacCarter discloses the following of claim 1:

1. A telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based physiological data acquisition and transmittal device comprises:

an electronic physiological data acquisition unit which, under the control of a patient measures a physiological parameter of the patient to acquire and output data representing the parameter (Fig. 1 data gathering device 108 as disclosed in paragraphs [0031] and [0032]);

a secure data store (Fig. 1 aggregation node 112 as disclosed in paragraphs [0037] and [0038]);

Art Unit: 3769

a wireless transmitter which upon receiving the output data from the data acquisition unit automatically transmits the output data via the wireless network to the remote server (abstract and paragraphs [0037] and [0040]); and

a display for displaying to the patient the data and messages related to the patient's condition (Fig. 3A paragraphs [0038] and [0050] aggregation node 112 comprises a display),

wherein the remote computer comprises a data analyzer and an automatic message generator to generate the messages (paragraphs [0054], [0082], and [0091] indicating automatic messaging based on "event thresholds" upon analyzing patient data), and

wherein the data analyzer automatically performs trend analysis of the data with reference to trends tuned to each patient's characteristics (paragraphs [0083] – [0091] indicating trend analysis on acquired physiological data).

MacCarter does not disclose acquiring and storing data when the wireless network is unavailable and automatically transmitting the stored data when a connection to the wireless network is available. However West, a reference in an analogous art, discloses a patient monitoring system comprising of wireless patient monitoring devices with automatic communication restoration capabilities (West paragraphs [0033] and [0097] – [0114]).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the data gathering devices of MacCarter with automatic communication restoration capability as disclosed in West, because West teaches the use of automatic communication restoration increases clinician efficiency by allowing a large number of patients to be monitored without constant intervention by medical personnel to reconfigure the patient monitoring devices after communication dropout occurs (West paragraph [0114]).

Art Unit: 3769

MacCarter discloses using trend analysis to automatically generate messages based on acquired physiological data and also assist medical professionals in formulating questions for the patient (MacCarter paragraphs [0039] and [0054]). MacCarter does not disclose automatically creating questions to initiate interaction with the patient and which are furthermore changeable by automatic download from a server in response to changes in the patient's condition. However Iliff, a reference in an analogous art, discloses medical diagnostic network with a script generator to automatically generate patient-specific messages and questions in response to medical data constantly being provided by the patient (paragraphs [0032] and [0127] - [0128]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the message generator as disclosed in MacCarter to generate questions that change based on the patient's condition as disclosed in Iliff, because Iliff teaches the use of a script generator developed by a consortium of medical experts to generate condition-specific questions can provide patients with more consistent expert and precise advice than a physician unfamiliar with the patient or the patient's condition (Iliff paragraphs [0023] and [0119] – [0120]).

Modified MacCarter in view of West and further in view of Iliff also disclose the following dependent claims:

2. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to receive automatically the output data from the physiological data acquisition unit on data acquisition thereby, and thereupon automatically to transmit the output data immediately in real time to the remote server if the connection to the wireless network is available (West paragraphs [0033] and [0097] – [0114] rejected for the same reasons as claim 1; establishment of an

Art Unit: 3769

automatic always-on connection as disclosed in West above reduces medical professional intervention).

3. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to establish a connection to the wireless network automatically when it is switched on and to maintain the connection while switched on (West paragraphs [0033] and [0097] – [0114] rejected for the same reasons as claim 1; establishment of an automatic always-on connection as disclosed in West above reduces medical professional intervention).

8. A telemedicine system according to claim 1 wherein the wireless transmitter is one of a cellular telephone and a PDA (MacCarter paragraphs [0040] and [0041]).

9. A telemedicine system according to claim 8 wherein a software application is provided on the one of a cellular telephone and a PDA to interface with the physiological data acquisition unit and to control data transmission to the remote server (MacCarter paragraphs [0040] and [0041]).

Claims 10, 11, and 14 are rejected for the same citation of West in claim 1 above, specifically paragraphs [0102] and [0103]. Part of the automatic reconnecting capability employed by West requires a quality check on data to determine what was successfully transferred, what data was lost, and if the data still belongs to the same patient.

Art Unit: 3769

15. A telemedicine system according to claim 1 wherein the remote server formats the data for delivery and display to a clinician (MacCarter paragraphs [0082] and [0083]).

18. A telemedicine system according to claim 1 wherein the physiological data acquisition unit is one of: an electronic flow meter for recording Peak Expiratory Flowrate, an electronic blood glucose meter, a blood pressure monitor, and a heart rate monitor (MacCarter paragraph [0032] physiological measurements acquired by the data gathering device include respiratory rate, heart rate, and blood pressure).

19. A telemedicine system according to claim 1 wherein the physiological data acquisition unit and wireless transmitter are integrated as a single device (MacCarter paragraph [0034] indicating a single solution data gathering device with a transmission portion and a data gathering portion).

23. A telemedicine system according to claim 1 wherein the data sent from the wireless transmitter is digitally signed (West paragraph [0111] a patient specific ID, which is equivalent to a digital signature, is attached to patient data and verified during the reconnecting process).

Claims 24 and 25 are rejected for the same citation of West in claim 1 above, specifically paragraphs [0100], [0112] and [0113]. Patient location is part of the data sent and provided to the clinician upon reconnection of the patient to the communication network to verify that data collected is still from the same patient.

Art Unit: 3769

27. A telemedicine system according to claim 1 wherein further information is sent from the server to the patient-based physiological data acquisition and transmittal device, and wherein in dependence upon the physiological parameter measurement and transmission to the server the further information comprises a prescription for medication (MacCarter paragraph [0091] trend analysis over patient data result in alerts that include changes in therapy by a clinician).

Claims 36 and 37 are rejected for substantially the same reasons as claim 1.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacCarter in view of West, further in view of Iliff as applied to claim 1 above, and further in view of Anthony et al. US Patent Application 2003/0063004 (hereinafter referred to as “Anthony”).

Modified MacCarter discloses the elements of claim 1 above, and further discloses the use of cellular data connections as an embodiment of the wireless network connecting the system together (MacCarter paragraph [0042]). MacCarter does not specifically disclose using a packet-switching public cellular data connection such as GPRS or 3G. However Anthony, a reference in an analogous art, discloses using such types of cellular data connections in mobile medical applications (Anthony paragraphs [0055], [0075], and [0091]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the cellular data network as disclosed in MacCarter with a GPRS or 3G network as disclosed in Anthony,

Art Unit: 3769

because Anthony teaches these network technologies as suitable connections for mobile medical applications requiring an “always on” connection (Anthony paragraphs [0055] and [0091]).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacCarter in view of West, further in view of Iliff as applied to claim 1 above, and further in view of Baker, Jr. et al. US Patent No. 5,853,364 (hereinafter Baker).

Modified MacCarter discloses the limitations of claim 1 above and further discloses the use of filters during patient trend analysis (MacCarter paragraph [0091]). Modified MacCarter does not disclose that the data analyzer comprises a Kalman smoother for smoothing the data. However Baker, a reference in an analogous art, discloses, in column 4, lines 4-25, the use of a Kalman filter to reduce noise energy in a system for measuring physiological parameters. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify MacCarter with the Kalman filter of Baker because Baker teaches in column 4, lines 4-25 and column 9, lines 58-60, that the Kalman filter optimally filters noise from physiological measurements and further teaches, in column 11, lines 22-36, that the Kalman filter improves accuracy of the results.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacCarter in view of West, further in view of Iliff as applied to claim 1 above, and further in view of Ginter et al. US Patent Application 2003/0191719 (hereinafter referred to as “Ginter”).

Art Unit: 3769

Modified MacCarter discloses the limitations of claim 1 above, and further discloses using secure methods of data transmission to protect patient privacy (MacCarter [0037]). MacCarter does not explicitly disclose using a secure clock in the devices of the remote monitoring system. However Ginter, a reference in an analogous art, discloses a system for securely transferring data using various security techniques including the use of a secure clock (Ginter paragraph [0574]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the devices of MacCarter with a secure clock for time referencing as disclosed in Ginter, because Ginter teaches the use of secured clocks is an efficient and effective method of securing medical information and maintaining patient privacy that can be implemented in standard off-the-shelf CPUs (Ginter paragraph [0574]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Soriano whose telephone number is (571)270-7030. The examiner can normally be reached on Monday thru Friday, 10:30am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3769

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Soriano/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
3769

March 13, 2010